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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/537,462 | 06/03/2005 | Kenji Matsuda | Q88123 | 4737 |

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

| EXAMINER | |
|---|---|
| SOROUSH, LAYLA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,462 | MATSUDA ET AL. | |
| | Examiner | Art Unit | |
| | Layla Soroush | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7-9,11-13,15-21,23-25,27-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-9, 11-13, 15-21, 23-25, 27-29, and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

In view of a pre-appeal conference prosecution is reopened. The response filed June 1, 2007 presents remarks and arguments submitted to the office action mailed April 16, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 102(a) rejection of claims 1-4, 13, 15, 16, 18-20, 29, 31, and 32 over Yamada et al. (Publication Date June 26, 2002), as evidenced by PDRHealth (see copy) is persuasive. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 5, 7-9,11,12, 21, 23-25, 27, 28, and 33 over Yamada et al. (Publication Date June 26, 2002), as evidenced by PDRHealth (see copy) and further in view of Unger et al. (US Pat. No. 6,090,800) is persuasive. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claim 17 over Yamada et al. (Publication Date June 26, 2002), as evidenced by PDRHealth (see copy) and further in view of in view of Yugari (US 20010047162 A1) is persuasive. Therefore, the rejection is herewith withdrawn.

Claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29, and 31-33 are pending.

Upon further consideration of the claims the following new rejections are made:

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 9, 13, 15, 18-21, 29, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamada et al. (Publication Date June 26, 2002—provided in previous action), as evidenced by M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj.1988).

The claimed invention is a fat emulsion with which a local anesthetic is mixed before use, and which comprises propofol, an oily component, and an emulsifier, the fat emulsion further comprising a specific stabilizer. The limitation "pain relieving," recited in claims 18-20, 29, 31, and 32 is a preamble and receives no patentable weight.

Yamada et al. discloses a fat emulsion preparation (page 7 [a technical field and background art]) in example 1, comprising lidocaine (local anesthetic), propofol, soybean oils (oily component), and egg yolk lecithin (stabilizers and emulsifier) (pages 16 and 17 [0017]).

Yamada et al.'s Example 1, relied upon for the rejection, meets every limitation of claims 1-4, 13, 15, 16, 18-20, 29, 31, and 32. More specifically, Example 1 teaches:

- Lidocaine (local anesthetic)
- Propofol
- Soy bean oil (oily component)
- Yolk lecithin (stabilizer and emulsifier)
- Polyoxyethylene (6) hydrogenated castor oil (emulsifier)

M Schneider teaches egg lecithin comprises phosphatidylcholine and saturated and unsaturated fatty acid compositions inclusive of palmitic, stearic, oleic, linoleic, linolenic, and arachidonic. Therefore, yolk lecithin, in Yamada et al. inherently comprise the phosphatidylinositol, phosphatidylethanolamine and the C10-22 linear or branched, saturated or unsaturated fatty acids.

The composition taught in the prior art has a final concentration of 0.1-0.5 w/v% lidocaine (local anesthetic), 0.5-2.0 w/v % propofol, about 5-20 w/v % of vegetable oil (oily component), 0.5-5 w/v% of phospholipids, and 0.05-0.5 w/v% stabilizer and emulsifier), (page 16, paragraph [0015]). The claimed ranges overlap with the ranges taught by the prior art.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8, 11,12, 16, 23-25, 27, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (Publication Date June 26, 2002) in view of M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj), as applied to claims 1-5, 9, 13, 15, 18-21, 29, and 31 and further in view of Unger et al. (US Pat. No. 6,090,800).

Yamada et al and M Schneider are as discussed above.

The limitation "pain relieving," recited in claims 21, 23-25, 27, and 28 is a preamble and receives no patentable weight.

Yamada et al. teaches phospholipids as a component of the fat emulsion composition in 0.5-5 w/v%. Therefore, the claimed ranges overlap with the ranges taught by the prior art reference.

Yamada does not specifically teach the composition comprising at least one phospholipid selected from the group consisting of phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, and phosphatidylserine wherein the fatty acid esterified to glycerol moiety is a C18-22 linear or branched, saturated or unsaturated fatty acid nor at least one phospholipid derivative selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C10-22 linear or branched, saturated or unsaturated fatty acid.

Unger et al. teaches distearoylphosphatidylglycerol (column 18, line 57) (claim 7), palmitic acid, stearic acid, oleic acid (column 18, lines 57-58), dioleoylphosphatidylethanolamine (column 23, line 5) and distearoylphosphatidylethanol-amine-polyethylene glycol 5000 (column 30, line 50-51) as suitable stabilizers in a drug composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate any phospholipid suitable for a drug composition into the claimed fat emulsion composition. The incorporation would have been motivated by the teachings in Unger et al. that the "stabilizers provide improved stability involving, for example, the maintenance of a relatively balanced condition, and may be exemplified,

for example, by increased resistance of the composition against destruction, decomposition, degradation, and the like (column 6 lines 59-67 and column 7 lines 1-3)." Therefore the skilled artisan would have had a reasonable expectation of producing a similar composition, which yields the same efficacy and properties as taught in the prior art references.

In reference to claim 33, the term "mixing" is within the purview of a skilled artisan. The composition as claimed is anticipated by the prior art reference and the method of mixing is obvious to one of ordinary skill in the art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (Publication Date June 26, 2002) as applied to 1-5, 9, 13, 15, 18-21, 29, and 31 above, and further in view of Yugari (US 20010047162 A1).

Yamada et al is as discussed above.

Yamada et al. does not expressively teach the fat emulsion containing container having a multi-compartment that is divided with a partition in such a manner as to allow the compartments to communicate with one another, which container comprises one compartment containing the fat emulsion and another compartment containing a local anaesthetic.

Yugari teaches an injection kit "made of multiple layered flexible plastic bag formed cylindrically (soft bag), and is separated into compartments by one or plural welded partition easy-to-peel seal." Further, the reference teaches different liquid medicine can be kept in each separated compartment and the pressure can break the

partition seals, just prior to its use. An example of a liquid (solvent) contained in a compartment is a fat emulsions.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to incorporate the fat emulsion into the claimed container. The incorporation would have been motivated by the teaching in Yugari that the injection kit enables to inject to a patient directly upon the preparation of the solution with the kit. Therefore the skilled artisan would have had a reasonable expectation of producing a similar effect as taught in the prior art reference.

***Response to Arguments***

Applicant's arguments filed June 1, 2007 have been fully.

Applicant's arguments, filed June 1, 2007, with respect to the rejection(s) of claim(s) 1-4, 13, 15, 16, 18-20, 29, 31, and 32 under Yamada et al. (Publication Date June 26, 2002), as evidenced by PDRHealth (see copy) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yamada et al. (Publication Date June 26, 2002—provided in previous action), as evidenced by M Schneider (Chapter Seven Fractionation and Purification of Lecithin. Lecithins:Sources, Manufacture & Uses. Edited by Szuhaj).

Applicant argues that the teaching of Yamada et al. is different from the claimed invention because the stabilizers utilized in the examples are different from the claimed

limitations of (a) to (d). Additionally, phosphatidylcholine is different from the claimed components (a) and (b).

In response, the prior art does in fact teach the same composition used in the same amount of the claimed invention. The Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical compound, the properties applicant discloses and/or claims are necessarily present.

Further applicant argues that egg lecithin does comprises fatty acids and if it did the amount would be far too small to effectively function as a stabilizer.

M Schneider teaches that egg lecithin comprises phosphatidylcholine in 0-2, phosphatidylethanolamine 12-16, and saturated and unsaturated fatty acid compositions inclusive of palmitic 27-29, stearic 14-17, oleic 35-38, linoleic 15-18, linolenic 0-1, and arachidonic 3-5. Hence, applicant's arguments are not persuasive. Also, see new rejections above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant argues

that Unger et al. teaches " a wide range of lipids as stabilizers are used for pharmaceutical compositions." Examiner states that Unger is solely used to show that the claimed lipids as stabilizers are well known in the prior art to be used in pharmaceutical compositions.

***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER